Influenza Vaccine Live Intranasal

AHFS Class: 80:12 — Vaccines (tofc-80)

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Alert:

On January 5, 2026, the US Department of Health and Human Services (HHS) announced the approval of a revised US childhood and adolescent immunization schedule (https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html (https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html)). Under the revised recommendations, CDC continues to organize the childhood immunization schedule in three distinct categories (Immunizations Recommended for All Children, Immunizations Recommended for Certain High-Risk Groups or Populations, and Immunizations Based on Shared Clinical Decision-Making) but changes individual vaccine placement within those categories. For additional information, see https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html (https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html) .

Introduction

Influenza vaccine live intranasal (LAIV3) stimulates active immunity to influenza virus infection.[1,] The vaccine contains live, attenuated (cold-adapted) influenza virus types A and type B representing strains likely to circulate in the US during the upcoming influenza season.[1,100,]

Uses

▪ Prevention of Seasonal Influenza A and B Virus Infections

Influenza vaccine live intranasal is used to stimulate active immunity for prevention of influenza disease caused by influenza virus subtypes A and B represented in the vaccine; the vaccine is FDA-labeled for use in individuals 2 through 49 years of age.[1,]

Influenza vaccine live intranasal has not been evaluated and is not recommended in individuals with altered immunocompetence.[1,100,]

Each year, influenza vaccines are formulated based on recommendations from the FDA, Centers for Disease Control and Prevention (CDC), and other experts to determine the optimal viral antigen composition of the vaccines for the upcoming (current) influenza season.[100,101,102,112,] All influenza vaccines available in the US for the 2025-26 season are trivalent formulations containing antigens representing influenza A (H1N1), influenza A (H3N2), and influenza B (Victoria lineage).[100,102,]

Clinical Perspective

The American Academy of Pediatrics (AAP) and other organizations provide annual recommendations for the use of seasonal influenza vaccines in the US.[100,111,112,] These organizations recommend annual influenza vaccination in *all* persons ≥6 months of age who do not have contraindications.[100,111,112,] The Centers for Disease Control and Prevention (CDC) recommend the influenza vaccine for children after shared clinical decision-making with a healthcare provider.[135,]

Various preparations of influenza virus vaccines are commercially available in the US, which differ based on method of manufacturer (egg-based versus cell culture-based), dose (standard versus high-dose), and route of administration (e.g., parenteral versus intranasal).[100,] These preparations can be grouped into 3 broad categories: inactivated influenza vaccines (IIV3), recombinant influenza vaccine (RIV3), and live attenuated virus vaccine (LAIV3).[100,] Inactivated influenza vaccines (IIV3) include standard-dose egg-based vaccines, a standard-dose cell culture-based influenza vaccine (ccIIV3), a high-dose egg-based vaccine (HD-IIV3), and an adjuvanted standard-dose egg-based vaccine (aIIV3).[100,] For the 2025–26 season, egg-based influenza vaccines available in the US contain hemagglutinin derived from an influenza A/Victoria/4897/2022 (H1N1)pdm09-like virus; an influenza A/Croatia/10136RV/2023 (H3N2)-like virus; and an influenza B/Austria/1359417/2021 (B/Victoria lineage)-like virus.[100,] For the 2025–26 season, cell culture-based inactivated (ccIIV3) and recombinant (RIV3) influenza vaccines in the US contain hemagglutinin derived from an influenza A/Wisconsin/67/2022 (H1N1)pdm09-like virus; an influenza A/District of Columbia/27/2023 (H3N2)-like virus; and an influenza B/Austria/1359417/2021 (B/Victoria lineage)-like virus.[100,] This composition reflects an update in the influenza A(H3N2) component compared with that contained in the vaccines available during the 2024-2025 season.[100,]

ACIP states that all persons ≥6 months of age may receive an age-appropriate influenza vaccine with the exception of solid organ transplant recipients 18 through 64 years of age who are receiving immunosuppressive medication regimens; these individuals may receive either high-dose inactivated influenza vaccine (HD-IIV3) or adjuvanted inactivated influenza vaccine (aIIV3) as acceptable options (without a preference over other age-appropriate IIV3s or RIV3).[100,] ACIP states that there are no preferential recommendations for any specific vaccine type when more than one licensed, recommended, and age-appropriate vaccine is available, with the exception of selection of influenza vaccines for individuals ≥65 years of age.[100,] Because influenza vaccines are often less effective in older adults, the higher dose vaccines or adjuvanted vaccine is recommended in this population.[100,] For the 2025-26 influenza season, ACIP recommends that adults ≥65 years preferentially receive trivalent high-dose inactivated influenza vaccine (HD-IIV3), trivalent recombinant influenza vaccine (RIV3), or trivalent adjuvanted inactivated influenza vaccine (aIIV3).[100,] If none of these vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used.[100,] Live attenuated influenza

vaccine (LAIV3) should not be used in immunocompromised persons, persons with certain medical conditions, or persons receiving, having recently received, or about to receive influenza antiviral medications; LAIV also should not be used during pregnancy.[100] Patients should consult their healthcare provider about available flu vaccine options.[101]

The American College of Obstetricians and Gynecologists (ACOG) provides recommendations for annual influenza vaccine in pregnant individuals.[21] Because the risks associated with influenza infection are increased in both pregnant patients and their newborns,[21] ACOG recommends that individuals who are or will be pregnant during the influenza season receive an inactivated or recombinant influenza vaccine as soon as the vaccines are available.[21]

The Center for Infectious Disease Research and Policy (CIDRAP) has established the Vaccine Integrity Project to provide evidence-based guidance on key immunizations for the upcoming respiratory season focusing on influenza, RSV, and COVID.[22] The Vaccine Integrity Project is an initiative to safeguard vaccine use in the US and disseminate evidence-based information for informed decision-making.[22] A multi-disciplinary group of experts has been convened to prepare recommendations for the upcoming 2025-2026 fall-winter respiratory season.[22] CIDRAP will provide updates on the initiative's progress as they become available.[22] For additional information see, https://www.cidrap.umn.edu/vaccine-integrity-project (https://www.cidrap.umn.edu/vaccine-integrity-project) .

Regarding the timing of influenza vaccination, ACIP states that for most individuals who need only 1 dose of influenza vaccine for the season, the vaccine should ideally be offered during September or October.[100] However, vaccination should continue after October and throughout the influenza season as long as influenza viruses are circulating and unexpired vaccine is available.[100] For most adults, vaccination during July and August generally should be avoided unless there is a concern that vaccination during the season might not be possible; however, vaccination during these months can be considered in children who require 2 doses, children who require only 1 dose but visit their healthcare provider during late summer before the start of the school year, and pregnant persons in the third trimester.[100]

Dosage and Administration

▪ General

Pretreatment Screening

Screen all individuals for contraindications and precautions to vaccination.[100,112]

Dispensing and Administration Precautions

When administered by a healthcare provider in a healthcare setting, appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of influenza vaccine live intranasal.[1]

When self-administered or administered by a caregiver, seek immediate medical attention if symptoms of an allergic reaction occur following administration of influenza vaccine live intranasal.[1]

▪ Administration

Influenza vaccine live intranasal is administered intranasally using the prefilled, single-use sprayer supplied by the manufacturer.[1]

The single-use sprayer is equipped with a nozzle that produces a fine mist that is primarily deposited in the nose and nasopharynx.[1]

Intranasal Administration

Influenza vaccine live intranasal is a colorless to pale yellow suspension and is clear to slightly cloudy.[1] The intranasal influenza vaccine should not be mixed with any other vaccine or solution.[134]

Influenza vaccine live intranasal may be self- or caregiver-administered for those who meet eligibility criteria or be administered by a healthcare provider.[2] The manufacturer states that individuals 2 through 17 years of age should not self-administer the vaccine.[1] The vaccine recipient should be placed in an upright position.[1] Approximately one-half the contents of the prefilled, single-use sprayer should be administered into each nostril.[1] Active inhalation (i.e., sniffing) by the patient is not required during administration of the intranasal influenza vaccine.[1] The manufacturer's labeling should be consulted for specific information regarding use of the sprayer.[1]

After influenza vaccine live intranasal has been administered, the sprayer should be disposed of carefully (i.e., discarded using standard procedures for medical waste).[1]

Influenza vaccine live intranasal may be given simultaneously with other age-appropriate vaccines during the same health-care visit.[134]

Store at 2–8°C; do not freeze.[1] A single temperature excursion up to 25°C for 12 hours has no adverse impact on the vaccine; however, after such an excursion, immediately return the vaccine to 2–8°C and use as soon as feasible.[1] Subsequent excursions are not permitted.[1] Influenza vaccine live intranasal does not contain thimerosal or any other preservatives.[1]

▪ Dosage

The dosing schedule (i.e., number of doses) of seasonal influenza vaccine live intranasal for prevention of seasonal influenza depends on the individual's age and vaccination history.[1]

A single dose of seasonal influenza vaccine live intranasal consists of the entire contents (0.2 mL) of the sprayer (approximately one-half of the contents or 0.1 mL in each nostril).[1]

Pediatric Dosage

Children 2 through 8 Years of Age.

Children 2 through 8 years of age who did *not receive a total of 2 or more doses* of any seasonal influenza vaccine before July 1, 2025 or whose previous influenza vaccination history is unknown: 2 doses of influenza vaccine live intranasal should be administered at least 4 weeks apart.[1,100,] Each dose consists of 0.2 mL (0.1 mL in each nostril).[1,] For children 8 years of age who require 2 doses of the vaccine, both doses should be administered even if the child turns 9 years between receipt of dose 1 and dose 2.[100,]

Children 2 through 8 years of age who received a total of 2 or more doses of any seasonal influenza vaccine ≥4 weeks apart before July 1, 2025: A single dose of influenza vaccine live intranasal consisting of 0.2 mL (0.1 mL in each nostril) is recommended.[1,100,]

Children 9 through 17 Years of Age.

For prevention of seasonal influenza in healthy children and adolescents 9 through 17 years of age, a single dose of influenza vaccine live intranasal consisting of 0.2 mL (0.1 mL in each nostril) should be administered.[1,100,]

Adult Dosage

Adults 18 through 49 Years of Age.

For prevention of seasonal influenza in nonpregnant adults 18 through 49 years of age, a single dose of influenza vaccine live intranasal consisting of 0.2 mL (0.1 mL in each nostril) should be administered.[1,100,]

▪ Special Populations

Geriatric Patients

Influenza vaccine live intranasal is *not* indicated in adults 50 years of age or older, including geriatric adults.[1,]

Cautions

▪ Contraindications

History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein.[1,]

History of severe allergic reaction (e.g., anaphylaxis) to a previous dose of any influenza vaccine.[1,]

Children and adolescents 2 through 17 years of age receiving aspirin or aspirin-containing therapy because of the association of Reye's syndrome with aspirin use and wild-type influenza infection.[1,]

▪ Warnings/Precautions

Risks in Children Younger than 24 Months of Age

Influenza vaccine live intranasal should *not* be used in infants younger than 24 months of age.[1,] An increased risk of wheezing and hospitalization was reported when the live intranasal vaccine was used in this age group in clinical trials.[1,]

In studies in infants, those 6–23 months of age had an increased incidence of wheezing (5.9%) within 42 days of receiving influenza vaccine live intranasal compared to the incidence in infants in this age group who received influenza virus vaccine inactivated (3.8%).[1,] In addition, an increase in hospitalizations (4.2%) within 180 days of vaccination with the live intranasal vaccine was observed in infants 6–23 months of age compared to the incidence in infants in this age group given influenza virus vaccine inactivated (3.2%).[1,] The incidence of wheezing (2.1%) or hospitalizations (2.1%) in children 24–59 months of age given the live intranasal vaccine was similar to the incidence in children in this age group given influenza virus vaccine inactivated (2.5% for wheezing and 2.5% for hospitalization).[1,]

Individuals with Asthma, Recurrent Wheezing, or Active Wheezing

Individuals of any age with asthma and children younger than 5 years of age with history of recurrent wheezing may be at increased risk of wheezing after receiving influenza vaccine live intranasal.[1,]

Influenza vaccine live intranasal has not been studied in individuals with severe asthma or active wheezing.[1,]

Experts state that influenza vaccine live intranasal should *not* be used in children 2 through 4 years of age with asthma or a history of wheezing in the past 12 months, and should be used with caution in individuals 5 years of age or older diagnosed with asthma.[100,112,]

Guillain-Barré Syndrome

If Guillain-Barré syndrome (GBS) occurred within 6 weeks after previous influenza vaccination, the manufacturer states that the decision to administer influenza vaccine live intranasal should be based on careful consideration of potential benefits and risks.[1,]

The 1976 swine influenza vaccine was associated with an elevated risk of GBS.[1,] Evidence for a causal relationship between other influenza vaccines and GBS is inconclusive; if an excess risk exists, it probably is slightly more than 1 additional case of GBS per 1 million vaccinees.[1,]

ACIP states that a history of GBS within 6 weeks after receipt of any influenza vaccine is a precaution to the use of all influenza vaccines.[100,]

Individuals with Altered Immunocompetence

The manufacturer states that efficacy of influenza vaccine live intranasal has not been studied in immunocompromised individuals.[1,]

Use of live, attenuated virus vaccines in individuals with altered immunocompetence may be associated with an increased risk for adverse reactions because of uninhibited growth of the live, attenuated vaccine virus.[134,] In addition, immune responses to vaccines may be reduced in immunosuppressed individuals.[134,]

ACIP states that influenza vaccine live intranasal should not be used in children and adults who are immunocompromised, including but not limited to immunosuppression caused by medications, congenital or acquired immunodeficiency states, HIV infection, anatomic asplenia, or functional asplenia such as that due to sickle cell anemia.[100,]

Because of possible transmission of live vaccine viruses, ACIP also states that influenza vaccine live intranasal should *not* be administered to close contacts of *severely* immunocompromised individuals who require care in a protective environment.[134,]

Although the effectiveness of influenza vaccine live intranasal in preventing influenza illness in HIV-infected individuals has not been evaluated, there is some evidence from studies in a limited number of HIV-infected adults, adolescents, and children that adverse effects and frequency and duration of vaccine virus shedding in such individuals are similar to that reported in healthy individuals.[1,]

Individuals with Medical Conditions Involving CSF Leak

ACIP states that influenza vaccine live intranasal should not be used in individuals with medical conditions that involve active communication between CSF and the oropharynx, nasopharynx, nose, or ear or any other cranial CSF leak.[100,] In addition, ACIP states that the live vaccine should not be used in individuals with cochlear implants because of the potential for CSF leak, which might exist for some period after implantation.[100,]

Individuals with Medical Conditions that Increase Risk of Influenza Complications

Safety of influenza vaccine live intranasal has *not* been established in individuals with underlying medical conditions known to increase the risk for complications following wild-type influenza infection.[1,]

ACIP states that influenza vaccine live intranasal should not be used in individuals with chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus).[100,]

Transmission of Vaccine Virus

Influenza vaccine live intranasal contains live, attenuated virus.[1,] Vaccine virus capable of infection and replication is present in nasal secretions of vaccine recipients, and viral shedding occurs in adults and children who have received the live intranasal influenza vaccine.[1,]

Data from several studies indicate that 50–69% of children 2–9 years of age, 29% of children and adolescents 9–17 years of age, and 20% of adults 18–49 years of age may shed one or more strains of vaccine virus within 28 days after receiving influenza vaccine live intranasal.[1,] The majority of vaccine virus shedding occurs within 2–3 days after vaccination with influenza vaccine live intranasal; only 1–3% of vaccine recipients 2–49 years of age shed one or more strains of vaccine virus after day 11.[1,]

Transmission of vaccine virus has occurred rarely between recipients of influenza vaccine live intranasal and their contacts.[1,] Based on limited data from a study that evaluated transmission of vaccine virus from young children who had received influenza vaccine live intranasal to unvaccinated young children in a day-care setting, the frequency of transmission of vaccine virus in such a setting was estimated to be 0.6–2.4%.[1,]

Concomitant Illness

The decision whether to administer or delay vaccination in an individual with a current or recent acute illness depends on the severity and etiology of the illness.[134,]

ACIP states that mild acute illness generally does not preclude vaccination.[134,] However, moderate or severe acute illness (with or without fever) is a precaution for vaccination and vaccines should be deferred until the individual has recovered from the acute phase of the illness.[134,] This precaution avoids superimposing adverse effects of the vaccine on the underlying illness or mistakenly concluding that a manifestation of the underlying illness resulted from vaccination.[134,]

If nasal congestion is present that might impede delivery of influenza vaccine live intranasal to the nasopharyngeal mucosa, AAP states that administration of the intranasal vaccine should be deferred; alternatively, a different age-appropriate influenza vaccine should be administered.[112,]

Hypersensitivity Reactions

Hypersensitivity reactions (e.g., anaphylactic reaction, facial edema, urticaria) have been reported after administration of influenza vaccine live intranasal.[1,] The manufacturer states that the vaccine is contraindicated in individuals who have experienced a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine including egg protein, or after a previous dose of any influenza vaccine.[1,]

Prior to administration of seasonal influenza vaccine live intranasal, the patient's immunization history regarding possible sensitivity reactions to the vaccine or vaccine components, including egg protein, and vaccination-related adverse effects should be reviewed to identify any contraindications and assess the risks and benefits of the vaccine.[100,112,134,] When administered by a healthcare provider in a healthcare setting, appropriate medical treatment and supervision must be available for immediate use in case an anaphylactic reaction occurs.[1,] When self-administered, seek immediate medical attention if symptoms of an allergic reaction occur following administration.[1,]

Although egg is a component of influenza vaccine live intranasal, ACIP states that all individuals aged ≥6 months with egg allergy should receive influenza vaccine with any influenza vaccine (egg-based or non-egg-based) that is otherwise appropriate for the recipient's age and health status.[100,] Egg allergy alone necessitates no additional safety measures for influenza vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg.[100,] Although egg allergy is neither a contraindication nor precaution to the use of any influenza vaccine, there are contraindications and precautions related to allergies to vaccine components other than egg and to previous allergic reactions to influenza vaccines[100,]

Limitations of Vaccine Effectiveness

Seasonal influenza vaccine live intranasal may not protect all vaccine recipients against influenza.[1,]

Specific Populations

Pregnancy.

The manufacturer states that influenza vaccine live intranasal is not absorbed systemically following intranasal administration and use in pregnant women is not expected to result in fetal exposure.[1] Animal reproduction studies performed with influenza vaccine live intranasal have not revealed evidence of harm to the fetus.[1]

Experts state that influenza vaccine live intranasal should *not* be used during pregnancy.[100] Women who are pregnant or who might become pregnant during the influenza season should be vaccinated using any licensed, age-appropriate, inactivated influenza vaccine (i.e., influenza virus vaccine inactivated or influenza vaccine recombinant).[100,112]

Lactation.

The manufacturer states that influenza vaccine live intranasal is not absorbed systemically following intranasal administration and distribution into milk is not expected.[1]

ACIP states that live, attenuated virus vaccines generally do not pose any unusual risks for women who are breast-feeding or their breast-fed infants.[134] Although live, attenuated viruses in vaccines can replicate in the mother, the majority of live vaccine viruses are not distributed into milk.[134]

Pediatric Use.

Safety and efficacy of influenza vaccine live intranasal have been established *only* in children 2 years of age or older.[1]

The effectiveness of influenza vaccine live intranasal in children 6 through 17 years of age is supported by demonstration of efficacy in younger children 6–71 months of age and effectiveness in adults 18–49 years of age.[1]

Influenza vaccine live intranasal should *not* be administered to infants younger than 24 months of age.[1] An increased incidence of wheezing and hospitalization has been reported in a clinical trial in **infants 6 through 23 months of age [off-label]**† who received influenza vaccine live intranasal compared with those who received parenteral influenza vaccine inactivated.[1]

Adults 50–64 Years of Age.

Influenza vaccine live intranasal is *not* indicated for use in adults 50–64 years of age.[1] In a multicenter, placebo-controlled study, the vaccine was not effective in this age group.[1]

Geriatric Use.

Influenza vaccine live intranasal is *not* indicated for use in geriatric individuals 65 years of age or older.[1]

▪ Common Adverse Effects

Adverse effects reported more frequently in adults 18 through 49 years of age receiving seasonal influenza vaccine live intranasal than in those receiving placebo include runny nose (44%), headache (40%), sore throat (28%), tiredness/weakness (26%), muscle aches (17%), cough (14%), chills (9%), nasal congestion (9%), and sinusitis (4%).[1]

Adverse effects reported more frequently in children 2 through 6 years of age receiving seasonal influenza vaccine live intranasal than in those receiving placebo include runny nose/nasal congestion (58%), decreased appetite (21%), irritability (21%), fever (16%), lethargy (14%), sore throat (11%), headache (9%), muscle aches (6%), and chills (4%).[1] Similar adverse effects were reported in older children and adolescents through 17 years of age; in addition, abdominal pain was reported in 12% and decreased activity reported in 6% of vaccine recipients.[1]

Drug Interactions

▪ Antiviral Agents

Safety and efficacy of concomitant use of seasonal influenza vaccine live intranasal with antiviral agents used for the treatment or prevention of influenza (e.g., baloxavir marboxil, oseltamivir, peramivir, zanamivir) have not been evaluated.[100] However, because influenza antivirals inhibit replication of influenza viruses, these antivirals may decrease immune responses to influenza vaccine live intranasal vaccine and reduce efficacy of the vaccine.[1,100]

Based on the half-life of the specific influenza antiviral, ACIP states that oseltamivir or zanamivir potentially could interfere with influenza vaccine live intranasal if these antivirals are administered within the previous 48 hours of vaccination; peramivir could interfere if administered within the previous 5 days; and baloxavir could interfere if administered within the previous 17 days.[100] These intervals for potential interference might be further prolonged in patients with medical conditions that delay drug clearance (e.g., renal insufficiency).[100] ACIP recommends that individuals who receive influenza antivirals during the period starting with the specified time before receipt of the vaccine through 2 weeks after vaccination should be revaccinated using an age-appropriate influenza virus vaccine inactivated or influenza vaccine recombinant.[100]

▪ Aspirin

Influenza vaccine live intranasal is contraindicated in children and adolescents 2 through 17 years of age receiving aspirin or aspirin-containing therapy because of the association of Reye's syndrome with aspirin use and wild-type influenza infection.[1] When influenza vaccine live intranasal is used in children and adolescents 2 through 17 years of age, aspirin and aspirin-containing products should be avoided for 4 weeks following vaccination, unless clearly needed.[1]

▪ Immune Globulins

ACIP states that influenza vaccine live intranasal may be given concurrently with or at any interval before or after immune globulin (immune globulin IM [IGIM], immune globulin IV [IGIV], immune globulin subcutaneous) or specific hyperimmune globulin (hepatitis B immune globulin [HBIG], rabies immune globulin [RIG], tetanus immune globulin [TIG], varicella zoster immune globulin [VZIG]).[134]

▪ Immunosuppressive Agents

Immunosuppressive agents (e.g., cancer chemotherapy, certain biologic response modifiers, corticosteroids, radiation) may decrease immune responses to influenza vaccine live intranasal and may increase the risk of adverse effects.[134,]

Live, attenuated virus vaccines generally should be administered at least 2–4 weeks prior to initiation of cancer chemotherapy or radiation therapy or deferred until at least 3 months after such therapy is discontinued.[134,]

In solid organ transplant recipients receiving immunosuppressive anti-rejection therapies, ACIP recommends that administration of live, attenuated virus vaccines be deferred until at least 2 months following discontinuance of such therapies.[134,]

Live, attenuated virus vaccines generally should be administered at least 2–4 weeks prior to initiation of treatment with anti-B-cell antibodies (e.g., rituximab).[134,] Some experts state that live, attenuated virus vaccines generally should be deferred until at least 6 months after treatment with anti-B-cell antibodies has been discontinued.[134,]

ACIP states that live, attenuated virus vaccines should be administered at least 2 weeks prior to initiation of therapy with certain other immunosuppressive biologic response modifiers (e.g., colony-stimulating factors, interleukins, tumor necrosis factor [TNF; TNF-α] blocking agents) or deferred until at least 3 months after such therapy is discontinued.[134,]

Because high-dose, systemic corticosteroid therapy (i.e., prednisone or equivalent in a dosage of at least 2 mg/kg daily or at least 20 mg daily given for 2 weeks or longer) is considered immunosuppressive, ACIP and other experts state that live, attenuated virus vaccines should be deferred for at least 1 month after such therapy is discontinued.[134,] ACIP states that live, attenuated virus vaccines generally do not need to be deferred in patients receiving corticosteroid therapy that is short-term (less than 2 weeks) or considered low- to moderate-dose systemic therapy (less than 20 mg of prednisone or equivalent daily); long-term, alternate-day, systemic corticosteroid therapy using short-acting drugs; maintenance physiologic doses of corticosteroids (replacement therapy); topical corticosteroid therapy (e.g., cutaneous, ophthalmic); or corticosteroids administered by oral inhalation or by intra-articular, bursal, or tendon injection.[134,]

▪ Intranasal Preparations

Data are not available regarding concomitant administration of influenza vaccine live intranasal with other preparations that are administered intranasally (e.g., intranasal corticosteroids).[1,]

▪ Vaccines

Inactivated Vaccines and Toxoids

ACIP states that, in the absence of specific data indicating interference, inactivated vaccines or toxoids can be administered simultaneously with or at any interval before or after influenza vaccine live intranasal.[134,]

Live Vaccines

ACIP states that influenza vaccine live intranasal and other live vaccines generally may be administered concurrently during the same health-care visit.[134,] However, because of theoretical concerns that the immune response to other live virus vaccines might be impaired if given within 28 days (4 weeks) of another live virus vaccine, ACIP states that if influenza vaccine live intranasal and other live vaccines are not administered on the same day, they should be administered at least 4 weeks apart.[134,] If a live vaccine is administered less than 4 weeks after a previous live vaccine, the second live vaccine administered should not be counted and the vaccine dose should be repeated at least 4 weeks later.[134,]

Measles, Mumps, Rubella, and Varicella Vaccines.

Influenza vaccine live intranasal may be administered concomitantly with measles, mumps, and rubella virus vaccines live (MMR) and varicella virus vaccine live (VAR).[134,] If not given concurrently, the vaccines should be administered at least 4 weeks apart.[134,]

Concomitant administration of influenza vaccine live intranasal with MMR and VAR has been studied in **infants 12 through 15 months of age [off-label]**†.[1,25,] There was no evidence of interference with the immune response to the measles, mumps, rubella, varicella, or influenza antigens, and adverse effects were similar to those reported in other clinical studies evaluating influenza vaccine live intranasal.[1,25,] Safety and immunogenicity of concomitant administration of these vaccines have not been specifically evaluated in infants older than 15 months of age.[1,]

Rotavirus Vaccines.

Concomitant administration of oral rotavirus vaccine live and influenza vaccine live intranasal has not been studied; however, rotavirus vaccine is not indicated in children 2 years of age or older (the age group that can receive the intranasal influenza vaccine).[26,]

Typhoid Vaccines.

Although specific data are not available, ACIP states that if typhoid vaccine live oral is warranted, it should not be delayed and may be administered simultaneously with or at any interval before or after other live vaccines (e.g., influenza vaccine live intranasal).[134,]

Description

Seasonal influenza vaccine live intranasal contains live, attenuated (cold-adapted) influenza virus types A and type B and is used to stimulate active immunity to influenza virus infection.[1,] The vaccine is prepared by culturing live attenuated influenza virus reassortants in specific pathogen-free eggs.[1,] Following administration of influenza vaccine live intranasal, vaccine virus replicates in cells lining the nasopharynx.[1,] The protective mechanism is not completely understood, but may involve both serum and

nasal secretory antibodies and cell-mediated immune responses (influenza-specific T-cells).[1,]

Each 0.2 mL of seasonal influenza vaccine live intranasal for the 2025-2026 influenza season contains $10^{6.5–7.5}$ FFU (fluorescent focus units) of each of the following live, attenuated influenza virus reassortants: A/Norway/31694/2022 (H1N1) (an A/Victoria/4897/2022 (H1N1)pdm09 - like virus), A/Perth/722/2024 (H3N2) (an A/Croatia/10136RV/2023 (H3N2) - like virus), and B/Austria/1359417/2021 (B/Victoria lineage) (a B/Austria/1359417/2021 (B/Victoria lineage) - like virus).[1,] Each 0.2-mL dose of the vaccine also contains monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, residual amounts of ovalbumin, and may also contain residual amounts of gentamicin sulfate and ethylenediaminetetraacetic acid (EDTA).[1,] Seasonal influenza vaccine live intranasal does not contain preservatives.[1,]

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from MedlinePlus (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus) (in English and Spanish; written at a 6th- to 8th-grade reading level).

Prior to administration of seasonal influenza vaccine live, provide a copy of the appropriate CDC Vaccine Information Statement (VIS) to the patient or patient's legal representative.[1,20,]

Advise the vaccine recipient or caregiver to read the FDA-approved patient labeling (Information for Patients and Their Caregivers).[1,]

When influenza vaccine live intranasal is self-administered or administered by a caregiver, instruct the vaccine recipient or caregiver to read the "Instructions for Use."[1,] Individuals 2 through 17 years of age should not self-administer the vaccine.[1,]

Advise patient and/or patient's parent or guardian of the risks and benefits of influenza vaccine live intranasal.[1,]

Ask patient and/or patient's parent or guardian if vaccinee has a history of asthma or recurrent wheezing.[1,] Advise patient's parent or guardian that a history of recurrent wheezing may be an asthma equivalent in children < 5 years of age and that individuals of any age with asthma and children < 5 years of age with recurrent wheezing may be at increased risk for wheezing after receiving the intranasal vaccine.[1,]

Advise patient and/or patient's parent or guardian that seasonal intranasal influenza vaccine is a live, attenuated virus vaccine and that vaccine virus can be transmitted to immunocompromised close contacts.[1,]

Instruct the vaccine recipient or caregiver to seek immediate medical attention if the vaccine recipient experiences any symptoms of an acute allergic reaction.[1,]

Inform clinicians of adverse effects.[1,] Clinicians or individuals can report any adverse reactions that occur following vaccination to the manufacturer at 877-633-4411 or Vaccine Adverse Event Reporting System (VAERS) at 800-822-7967 or https://vaers.hhs.gov/index (https://vaers.hhs.gov/index) .[1,]

Stress importance of informing clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs, as well as concomitant illnesses (i.e., asthma, recurrent wheezing, GBS).[1,]

Stress importance of women informing clinician if they are or plan to become pregnant or plan to breast-feed.[1,]

Inform patients of other important precautionary information.[1,]

Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The manufacturer's labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Influenza Vaccine Live Intranasal (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Influenza+Vaccine+Live+Intranasal&collapse=1)

Nasal

Suspension

$10^{6.5–7.5}$ FFU (fluorescent focus units) each of FDA-specified influenza A (H1N1), influenza A (H3N2), and influenza B/Victoria lineage antigens per 0.2 mL

FluMist® 2025-2026 Formula *(available as prefilled single-dose intranasal sprayer)*, MedImmune (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=LabelerName&ApptName=MedImmune&collapse=1)

Related Resources

AHFS Patient Medication Information (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?

v:project=medlineplus&query=Influenza%20Vaccine%20Live%20Intranasal) and other related patient health topics (MedlinePlus)
ASHP Drug Shortages Resource Center (https://www.ashp.org/Drug-Shortages)
CCRIS (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+ccris:%%22Influenza%20Vaccine%20Live%20Intranasal%%22) (Chemical Carcinogenesis Research Information System)
ChemID*plus* (https://chem.nlm.nih.gov/chemidplus/name/Influenza%20Vaccine%20Live%20Intranasal)
Biochemical Data Summary (http://www.drugbank.ca/unearth/q?utf8=%%E2%%9C%%93&query=Influenza%20Vaccine%20Live%20Intranasal&searcher=drugs&approved=1&vet_approved=1&nutraceutical=1&illicit=1&withd (US and Canada)
Clinical Trials (https://www.clinicaltrials.gov/ct/search?submit=Search&term=Influenza%20Vaccine%20Live%20Intranasal)
DailyMed (https://dailymed.nlm.nih.gov/dailymed/search.cfm?query=Influenza%20Vaccine%20Live%20Intranasal) (drug labels)
DART (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+dart:%%22Influenza%20Vaccine%20Live%20Intranasal%%22) (Developmental and Reproductive Toxicology Database)
Drugs@FDA (https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchType=BasicSearch&SearchTerm=Influenza%20Vaccine%20Live%20Intranasal) (approval information)
European Medicines Agency (https://www.ema.europa.eu/en/search/search?search_api_views_fulltext=Influenza%20Vaccine%20Live%20Intranasal)
FDA National Drug Code Directory (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Influenza%20Vaccine%20Live%20Intranasal&collapse=1)
FDA Recalls, Market Withdrawals, and Safety Alerts (https://www.fda.gov/Safety/Recalls/default.htm)
HSDB (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:%%22Influenza%20Vaccine%20Live%20Intranasal%%22) (Hazardous Substances Data Bank)
Inxight Drugs (https://drugs.ncats.io/substances?q=%%22Influenza%20Vaccine%20Live%20Intranasal%%22) (National Center for Advancing Translational Sciences)
LactMed (drug effects on breastfeeding) (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+lactmed:@or+%%28@na+%%22Influenza%20Vaccine%20Live%20Intranasal%%22+%%29)
New Drug Approvals (https://ahfs.ashp.org/drug-assignments.aspx)
Orange Book (https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?panel=0&drugname=Influenza%20Vaccine%20Live%20Intranasal) (therapeutic equivalence)
PharmGKB (https://www.pharmgkb.org/search?connections&gaSearch=Influenza%20Vaccine%20Live%20Intranasal&query=Influenza%20Vaccine%20Live%20Intranasal&type=chemical) (Pharmacogenomic data from PharmGKB)
Pillbox (*beta*) (https://pillbox.nlm.nih.gov/pillimage/search_results.php?submit=Search&splid=&getingredient=Influenza%20Vaccine%20Live%20Intranasal) (drug identification and images)
PubMed (https://www.ncbi.nlm.nih.gov/pubmed?DB=pubmed&term=Influenza%20Vaccine%20Live%20Intranasal%%5BAll+Fields%%5D) (scientific journals)
Safety-related Labeling Changes (https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges) (FDA/CDER)
ToxLine (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+toxline:%%22Influenza%20Vaccine%20Live%20Intranasal%%22) (Toxicology Literature Online)

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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About ASHP
ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 55,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website (https://www.ashp.org), or its consumer website (https://www.safemedication.com).

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